

HQ



(12) PATENT ABRIDGMENT (11) Document No. AU-B-12654/95
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 685559

- (54) Title
ATRIAL MAPPING AND ABLATION CATHETER SYSTEM
- International Patent Classification(s)
(51)^e A61B 005/04
- (21) Application No. : 12654/95 (22) Application Date : 01.12.94
- (87) PCT Publication Number : WO95/15115
- (30) Priority Data
- (31) Number (32) Date (33) Country
181920 03.12.93 US UNITED STATES OF AMERICA
- (43) Publication Date : 19.06.95
- (44) Publication Date of Accepted Application : 22.01.98
- (71) Applicant(s)
BOAZ AVITALL
- (72) Inventor(s)
BOAZ AVITALL
- (74) Attorney or Agent
GRIFFITH HACK, GPO Box 4164, SYDNEY NSW 2001
- (56) Prior Art Documents
US 4699147
US 5228442
US 4660571
- (57) Claim

1. A recording and ablation catheter system for a vascular cardiac catheter for creating linear lesions to produce segmentation in a heart chamber comprising:
- (a) a hollow elongated vascular catheter or sheath having a lumen for containing an inner catheter;
 - (b) a vascular navigating guide member disposed to protrude from a distal end of said catheter or sheath;
 - (c) an inner catheter comprising a single member flexible distal working catheter section having a proximal and a distal end and adapted to be deployed from said elongated catheter or sheath in a heart chamber, said distal working catheter section being contained at the proximal end having a plurality of spaced separately connected serially situated electrodes on said single member working catheter section; and
 - (d) means enabling said working catheter section to assume an arcuate shape of controlled curvature for contacting an internal surface of said chamber.

(11) AU-B-12654/95
(10) 685559

-2-

21. A method of mapping and ablating surface tissue in the right atrial cardiac chamber comprising the steps of:

- (a) navigating a main catheter or sheath carrying a deployable flexible distal working catheter section through the vascular system of a patient of interest;
- (b) causing the distal end of the catheter to enter the right atrial chamber optionally through a vessel selected from the group consisting of the superior vena cava and the inferior vena cava;
- (c) wherein said main catheter or sheath comprises:
 - (1) a vascular navigating guidewire disposed to protrude from a distal end of said main catheter or sheath;
 - (2) a single member flexible working catheter section having a proximal and a distal end and adapted to be deployed from said main catheter or sheath via a lumen therein for containing said working catheter section and a plurality of spaced separately connected serially stimulation electrodes on said single member working catheter section;
 - (3) means for causing said working catheter section to assume an arcuate shape of controlled curvature for contacting an internal surface of said chamber and assuming an adjustable posture enabling positioning for the production of substantially linear ablation lesions along a predetermined line of the chamber surface using said plurality of spaced electrodes.
- (d) causing the distal area of the working catheter section to assume a controlled curvature in contact with a desired inner atrial surface such that a relatively linear ablation lesion can be formed by energising a plurality of said spaced serial electrodes;

(11) AU-B-12654/95
(10) 685559

-3-

- (e) adjusting and positioning said single member working catheter section to ablate desired areas of said inner atrial surface;
- (f) ablating tissue to form linear lesions where indicated; and
- (g) reversing steps (b) and (a).

OPI DATE 19/06/95 APPLN. ID 12654/95
ACJP DATE 10/08/95 PCT NUMBER PCT/US94/13932



AU9512654

(51) International Patent Classification ^b : A61B 5/04	A1	(11) International Publication Number: WO 95/15115 (43) International Publication Date: 8 June 1995 (08.06.95)
--	----	---

(21) International Application Number: PCT/US94/13932

(22) International Filing Date: 1 December 1994 (01.12.94)

(30) Priority Data:
08/161,920 3 December 1993 (03.12.93) US

(71)(72) Applicant and Inventor: AVITALL, Boaz [US US]; 4868 North Ardmore Avenue, Milwaukee, WI 53217 (US).

(74) Agent: MERSEREAU, C., G.; Haugen and Nikolai, P.A., 820 International Centre, 900 Second Avenue South, Minneapolis, MN 55402 (US).

(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

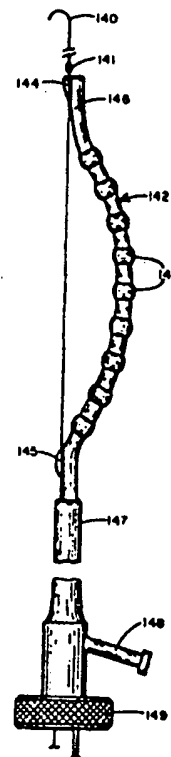
*With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

985559

(54) Title: ATRIAL MAPPING AND ABLATION CATHETER SYSTEM

(57) Abstract

A recording and ablation catheter system for creating linear lesions in the right atrial chamber of a heart is disclosed which includes an array of readily controlled electrodes (143) arcuate distal working catheter shapes that are easily deployed to contact the inner wall surface of the recording and mapping of impulses and thereafter facilitates sustained contact so that linear lesions can be produced from an array of mapping and ablation electrode devices (143) serially spaced along the working catheter shape.



PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



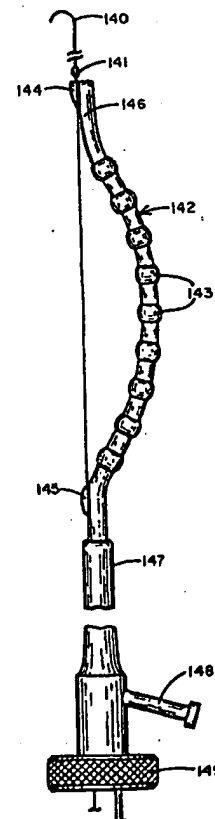
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 5/04		A1	(11) International Publication Number: WO 95/15115
			(43) International Publication Date: 8 June 1995 (08.06.95)
(21) International Application Number: PCT/US94/13932		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(22) International Filing Date: 1 December 1994 (01.12.94)			
(30) Priority Data: 08/161,920 3 December 1993 (03.12.93) US			
(71)(72) Applicant and Inventor: AVITALL, Boaz [US/US]; 4868 North Ardmore Avenue, Milwaukee, WI 53217 (US).			
(74) Agent: MERSEREAU, C., G.; Haugen and Nikolai, P.A., 820 International Centre, 900 Second Avenue South, Minneapolis, MN 55402 (US).			

(54) Title: ATRIAL MAPPING AND ABLATION CATHETER SYSTEM

(57) Abstract

A recording and ablation catheter system for creating linear lesions in the right atrial chamber of a heart is disclosed which includes an array of readily controlled electrodes (143) arcuate distal working catheter shapes that are easily deployed to contact the inner wall surface of the recording and mapping of impulses and thereafter facilitates sustained contact so that linear lesions can be produced from an array of mapping and ablation electrode devices (143) serially spaced along the working catheter shape.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

ATRIAL MAPPING AND ABLATION CATHETER SYSTEM**BACKGROUND OF THE INVENTION****I. Field of the Invention**

The present invention relates generally to the field
5 of mapping and ablation using steerable vascular catheters.
The invention is particularly directed to an atrial mapping
and ablation catheter system for the creation of linear
continuous lesions.

II. Discussion of the Related Art

10 Steerable catheter systems of several types have been
devised. Such devices can be inserted into blood vessels
or similar bodily areas and their distal ends navigated
through the tortuous vascular path to reach areas of the
body normally inaccessible without surgery. Catheters of
15 the steerable or self-navigating type, having distal
electroded sections for monitoring parts of the body, such
as for electrically mapping the heart by receiving and
transmitting electrical signals related to the operation of
that organ to recording signal processing and display
20 devices are also known. The ability to successfully record
impulses or signals and from them electrically map the
cardiac chambers and valves using flexible catheters having
steerable electroded tips has further led to the use of the
technique of transcatheter ablation of cardiac tissues that
25 have been identified as the pathways that cause cardiac
arrhythmias. This technique has emerged as one of the most
important advances in cardiac electrophysiology. Its goal
is to destroy the arrhythmogenic tissue without
compromising the mechanical or muscular integrity of the
30 cardiac tissues and vessels.

Not long ago, for example, many patients with Wolff-
Parkinson-White syndrome or ventricular tachycardia
underwent surgical dissection of the arrhythmogenic tissue
followed by a painful and prolonged recovery. Introduction
35 of the transcatheter approach has dramatically reduced the
suffering and cost of this definitive treatment for many
causes of cardiac arrhythmias.

The general approach to this procedure initially preferably utilized high energy direct current delivered to the catheter poles, for example, to disrupt the A-V node condition and even to create a complete heart block by ablating the His bundle. More recently, however, radio frequency has replaced high energy direct current as the preferred primary source of energy and the transcatheter approach for cardiac ablation has become an accepted and common procedure and has been used increasingly as the primary mode of treating cardiac arrhythmias. Transcatheter cardiac tissue ablation is more fully discussed in Avitall et al, "Physics and Engineering of Transcatheter Tissue Ablation", JACC, Volume 22, No. 3:921-32. The rapid clinical acceptance of this procedure and the proliferation of physicians engaged in transcatheter tissue ablation has mandated the development of improved steerable catheter devices.

Other common cardiac arrhythmias untreatable except with medication, and more recently, surgery, involve atrial fibrillation and flutter. These conditions, in fact, are the most common rhythm disturbances in human beings. For example, approximately 1% of the population of the United States, i.e., more than 2.5 million people, depends on medication to control this condition. These irregular heart rhythms can reach rates of 180 beats/minute or more. The resulting loss of blood flow due to incomplete atrial contractions along with a rapid heart rate can lead to shortness of breath, dizziness, limited physical endurance, chest pains, in patients with coronary heart disease, and other related problems.

Recently, Dr. Cox et al of Washington University School of Medicine in St. Louis, Missouri, have devised a surgical procedure called the Maze and Corridor operation. This procedure is an attempt to restore the normal heart rhythm by segmenting the atrial tissues in a manner that allows the normal heart pacemaker to conduct to the AV node as well as preventing the atrial tissues from sustaining

the atrial fibrillation. By cutting the atrial tissue, no electrical activity can be transmitted from one segment to another, thus making the segments too small to be able to sustain the fibrillatory process. The approach, while
5 successful, has the same drawbacks as other previous surgical approaches with respect to the recovery of the patient. This represents another area of cardiac arrhythmic treatment where a more benign approach, i.e., without invasive surgery, would represent a definite
10 advance.

In this regard, as with certain other arrhythmia conditions, electrical decoupling of tissues by heating the tissues with radio frequency (RF) energy, microwave energy, laser energy, freezing and sonication, represent possible
15 alternative approaches. Heating tissues above 55°C is known to cause permanent cellular injury, making the cells electrically silent. It has been found that segmenting tissues by creating continuous linear lesions via ablation in the atria mimics some aspects of the maze and corridor
20 procedure. The most important aspect of these lesions is their transmural and continuous character; otherwise, segmenting the heart and preventing atrial fibrillation would not be possible. However, it is possible that limited division of tissues within the right atrium may
25 prevent atrial fibrillation in some patients. Furthermore, segmenting a corridor between the sinus node and the AV node will maintain physiological control of heart rate despite the fibrillation of the atrial tissues.

Present steerable catheter systems, while successful
30 in addressing many internal cardiac areas, have not been so successful in treating atrial fibrillation because they have not been able to contact certain surface areas of the right atrial chamber without great difficulty. In this regard, prior devices have failed to successfully create
35 the necessary linear lesions via ablation to achieve the desired segmentation. The provision of a mapping and ablation catheter system that can successfully treat atrial

fibrillation and flutter as by readily creating linear continuous lesions in the atria would represent a definite advance in the treatment of this condition.

Accordingly, it is a primary object of the invention
5 to provide an improved catheter, easily deployed and maneuvered to contact desired inner wall surfaces of the right atrial cardiac chamber and sustain contact so that linear lesions can be produced as required.

Another object is to provide multi-electrode working
10 catheter shapes that are easily deployed from sheaths or main catheters once the desired atrial chamber is reached.

An additional object of the invention is to provide such catheter shapes capable of being readily modified to address internal surfaces of varying contour in a linear
15 manner.

Yet another object of the invention is to provide a method of readily mapping and ablating in the right atrial chamber.

Other objects and advantages of the invention will
20 become apparent to those skilled in the art in accordance with the descriptions and Figures of this specification.

SUMMARY OF THE INVENTION

By means of the present invention, there is provided an array of readily controlled arcuate distal working
25 catheter shapes that are easily deployed to contact the inner wall surface of the right atrial cardiac chamber in a manner that allows them to adapt to the endocardial surface of the right atrium and enables easy recording or mapping of impulses and thereafter facilitates sustained
30 contact so that linear lesions can be produced from an array of mapping and ablation electrode devices serially spaced along the working catheter shape using the electric heating or radio frequency ablation energy. The working catheter section is deployed from a main catheter or sheath
35 using any of several posturing techniques and assumes several deployed shapes, the control of which may be independent of or with reference to the slidable attachment

of one or both ends of the working catheter section to a guidewire or other catheter mounted element.

The working catheter of the invention may be deployed independently of or may include one or more rider devices which slidably thread over a wire member, which may be the guidewire, and which cooperate with stops limiting travel of at least one of the rider members such that adjustable arcuate forms are assumed by the section intermediate the rider members as their relative separation distance is modulated. In another alternate embodiment, a right- or left-handed loop shape is assumed by the specialty shaped working catheter upon deployment.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, wherein like numerals designate like parts throughout the same:

FIGURE 1 is a schematic representation of one embodiment of an atrial fibrillation mapping and ablation catheter in accordance with the invention with the extended length of the main tube segment broken away;

FIGURES 2-4 illustrate a different embodiment of a mapping and ablation catheter;

FIGURE 5 illustrates schematically the deployment of the catheter embodiment of Figure 1 in a right atrial chamber;

FIGURES 6 and 7 depict the deployment of the embodiment of Figure 8 in a right atrial chamber;

FIGURE 8 is an enlarged schematic representation of an alternate to the embodiment of Figures 2-4 of a working catheter in accordance with the invention with the elongated sheath shown broken;

FIGURE 9 is a schematic representation of yet a different embodiment of the catheter of the invention;

FIGURE 10 is an enlarged fragmentary view illustrating an infusion port usable with the catheter system of the invention; and

FIGURES 11-13 are fragmentary views of yet a different embodiment of the catheter of the invention which takes the form of a loop configuration when deployed.

DETAILED DESCRIPTION

5 The atrial fibrillation electrical mapping and ablation system is carried by a distal working catheter portion, extension or segment which, in accordance with the invention, may present itself in any of several forms. The distal portion or area is normally deployed from a main
10 catheter or sheath in the vicinity of the right atrium or other chamber of interest. The electrode position and form chosen will depend on the particular surface to be addressed and the mode of access to the chamber. Also, the electrode configuration is not meant to be limited in any
15 manner to the illustrated patterns, it being further understood that any size and pattern of electrodes consistent with mapping and ablation in any part of the chamber of interest can be employed.

 The electrode systems in accordance with the distal
20 working catheter section are generally designed so that each individual electrode is electrically connected by a separate insulated lead threaded through the catheter system to the distal end thereof where each lead is connected to a control system that enables separate mapping
25 or recording of impulses received from each electrode and separate or ganged connection of the same electrodes for ablation. This enables ablation using any desired pattern of multiple electrodes in the serial array to produce any configuration of desired lesions. Such an arrangement of
30 electrode control is illustrated and described in applicant's co-pending application Serial No. 08/_____ filed of even date herewith.

 The working catheter of the invention is designed to enable the skilled practitioner to achieve a greater degree
35 of control with respect to mapping and precisely placing linear lesions in the internal surface of tissue in the vicinity of the right atrial chamber with greater facility

using RF ablation or the like to achieve electrical segmentation. This is achieved by the provision of a variety of unique working catheter embodiments configured to contact continuous segments of atrial chamber surfaces.

- 5 While the embodiments will be described with particular reference to the right atrial cardiac chamber, it will be understood that the working catheters of the invention may find further use in other chambers and organs.

Such a catheter, shown generally at 20 in Figure 1, includes three main cooperating components including a distal working catheter sheath section or portion 22, which may be an extension of an elongated main tubular catheter member 24 shown broken to indicate the relatively extensive length, and a control handle 26 with a working tip manipulation or orientation control knob as at 28. The working catheter sheath section is provided with a slotted opening 30 from which a flexible segment or relatively short distal length of working catheter 32 which can readily be deflected or bent and which carries a plurality of serially spaced electrodes as at 34 emerges to be deployed. The control knob 28 may be attached to deploy and spatially manipulate (deflect and rotate) the working catheter section 32 in any well-known manner. One such control system is illustrated and described in the applicant's copending application Serial Number 08/_____ filed November 22, 1993, entitled Catheter Control Handle. Material from that application to the extent helpful or necessary to this description is further deemed incorporated herein by reference. In any event, the working catheter portion 32 is deployed from the sheath opening 30 and is designed to be manipulated both as to curvature and posture to position the electrodes against a surface to be mapped or ablated.

The catheter 20 further includes a short relatively flexible vascular guide member 36 fixed to the distal tip thereof to enable the device to be essentially self-navigating. A liquid-tight sheath locking device 37 with

infusion port 38 is provided proximal the point of catheter introduction which cooperates with an introducer device in a well-known manner such that catheter controls and input/output devices are accessible from outside or proximal the point of catheter introduction. A plurality of conductors are shown at 39.

Figure 5 is a schematic representation of a heart sectioned through the chambers including a right atrial chamber 42, right ventricle 44, separated by tricuspid valve 46. The pulmonary valve and artery are shown, respectively, at 48 and 50. The superior vena cava is shown at 52 and the inferior vena cava, at 54. The working catheter section is shown in the right atrium and extending in the vena cava and illustrates that the right atrial chamber 42 can be accessed either through the superior vena cava or the inferior vena cava and the electroded working segment deployed in conjunction with movement of the sheath 22 to enable placement of the electrodes 34 as desired.

Figures 2-4 depict an alternative functional embodiment 120 of the catheter/sheath of the invention in which the guidewire 122 protrudes from a closed distal end 124. The sheath section or portion 125 is provided with an elongated slot or opening 126 through which the working catheter section 127 with a plurality of electrodes 128 is deployed. As better seen in Figure 3, in this embodiment the guide member 122 extends into the lumen 129 of the sheath 125 and is further slidably threaded through a bore 130 in a rider segment 131 in the distal end of the working catheter section 127.

The working catheter section 127 has the rider of its distal end slidably threaded over the vascular guide member so that the more proximal portion of the catheter section 127 produces an adjustable arcuate curve in the electroded working catheter section. A control wire attached in the proximal area of the distal working catheter section in a well-known manner as, for example, described in the above cross-referenced copending applications, when reciprocally

manipulated as by handle 28 will produce an arcuate curve of varying severity as illustrated in Figures 3 and 4. In this manner, the plurality of serially spaced electrodes 128 can be caused to assume an adjustable pattern that can be placed adjacent chamber surfaces of varying arcuate shapes; Figure 4 illustrates a plurality of possible configurations. The nose portion 124 provides a distal stop that determines the furthest distal location of the tip rider 131 of the distal catheter segment 126 so that further distal directed longitudinal displacement of the proximal portion of the working catheter within the sheath will produce arcuate deflections to form configurations such as those illustrated.

Figure 8 is an enlarged schematic view of a guide-mounted embodiment using a slideover-type flexible guiding, navigation member or wire 140 over which the working catheter section 142 with electrodes 143 is threaded both distal and proximal the electroded portion using rider segments as illustrated at 144 and 145, respectively, leaving the central portion detached to form a "caterpillar" attachment arrangement. A positive stop 141 attached to the guide member 140 limits the distal travel of the catheter tip. The main catheter sheath is shown at 147, broken away for convenience, and optionally provided with an infusion port 148 with lock system 149.

The number, size and spacing of the electrodes 143 is optional. One embodiment used 20 ring electrodes about 4 mm long, spaced 4 mm apart. It will be appreciated, however, that the serially spaced electrode configuration in accordance with the invention and its several embodiments has as a primary goal, aside from arcuate tissue mapping or recording, the creation of linear lesions by means of ablation to achieve segmentation of conduction paths within the chamber surface tissue. With this in mind, certain combinations of electrode configurations and shapes can be employed. Electrodes 2 mm in length spaced 0.5-3 mm apart in the embodiments of Figures 1-4 and 9 have

also been used as have electrodes arranged in spaced pairs as in Figures 11-13.

The embodiment of Figure 8 is further illustrated with respect to placement in the right atrial chamber of a heart in Figures 6 and 7. These schematic sectional views illustrate that the relative arcuate shape of the mapping/ablation working catheter section 142 can be controlled to any desired shape and that such arcuate shapes very closely resemble the contour shapes of the internal surfaces of the various walls of the right atrium. In Figure 6, for example, the upper interior section 150 is readily addressed by the arcuate shape assumed by the working catheter section 142 as is the lower segment 152. In Figure 7, the right wall of the atrial chamber is addressed at 154. The working catheter section has further been rotated with respect to the guide member 140. These positions can be maintained despite continuously flowing blood and moving chamber walls.

With respect to the embodiment of Figure 8, a 7F sliding catheter system similar to that of Figure 8 was constructed that allowed the catheter to curve and adapt to the endocardial surface of the right atrium. The catheter was equipped with 20 closely spaced 4 mm electrodes used for both mapping and ablation. In 7 models, susceptibility to AFIB was created by sterile pericarditis, vagal stimulation and isuprel infusion (3 μ gram/min). A stiff guidewire with a floppy pigtail tip (as at 140 in Figure 8) was inserted via the femoral vein into the superior vena cava. A sheath was placed over the guidewire with its tip at the inferior vena cava/right atrial junction. The ablation catheter was inserted into the sheath over the guidewire and initially positioned at the posterolateral right atrium with the electrodes in contact with the superior vena cava, right atrium and inferior vena cava tissues. Catheter deflection was achieved by pushing the catheter shaft against a stopper located 10 cm from the guidewire tip. Graded RF power starting at 20 watts and

-11-

proceeding to 30, 40 and 50 watts was applied to each electrode for 30 seconds at each power level. Following the ablation, the catheter was moved and curved over the anterior wall of the right atrium and the ablations were repeated. AFIB was induced at least 10 consecutive times before and after ablation using 60 Hz alternating current applied for 5 seconds to the left atrial appendage. Six of the 7 models had sustained AFIB (> 3 min). Following the ablation, AFIB could not be sustained and lasted only 20±48 seconds. Examination of each heart revealed continuous transmural lesions bisecting the right atrium posterolaterally and anteriorly.

Figure 9 illustrates yet another embodiment in which the distal end or tip 160 of the working catheter segment 161 with electrodes 162 is deployed from a guided distal opening 163 in the distal end of a lumen 165 in a catheter or sheath 166 equipped with a flexible soft wire tip-type vascular guide member 167. In this embodiment, as with the embodiment of Figure 1, the amount of deployment, deflection and posture of the working catheter tip section 160 may be controlled by handle manipulations means in conjunction with one or more control wires or elements (not shown).

Figures 11-13 depict yet another configuration for providing an arcuate shape suitable for mapping and ablation within the confines of the right atrial chamber of the heart. As can be seen in those Figures, the distal end 170 of a distal working catheter section 171 emanating from a sheath or main catheter 172 at 173 has a bore slidably threaded through a flexible guidewire 174 provided with a positive stop member 175 fixed a predetermined distance from the distal navigating tip end of the guidewire 174. A control wire (not shown) attached through the working catheter 172 is used to axially adjust the position of the proximal end of the working catheter section 172 in relation to the stop to thereby form and adjust the relative size of the essentially circular loop 176. In

-12-

this manner, the loop 176, 176A may be made larger or smaller in a given set amount thereby enabling it to address right atrial chambers of different sizes and be expanded against arcuate shapes of varying radii. It can also assume a substantially linear shape prior to or after deployment to be retracted into the catheter or sheath. Whereas the electrodes 177 are depicted in spaced pairs, other configurations such as that of Figure 8 can be used.

Figures 11 and 12 depict opposite-handed circular loops which can be formed from the working catheter shown broken in Figure 13. The device may be predisposed to form a right- or left-handed loop with regard to a given orientation of the catheter and depending on the direction of entry into the right atrium and/or the particular surface to be mapped and/or ablated, one or the other might be preferable. Otherwise, the two are the same.

With respect to the dimensions of the various embodiments of the catheters of the invention, the working catheter segments are typically about 5 French to 8 French in diameter and the sheath member is approximately 7-10 French in diameter. The catheters having sheath or side openings, typically extend approximately 5 mm beyond the openings 30, 126, etc. and approximately 15 cm beyond the opening in the embodiment of Figure 9. The working catheter segments are typically 5-15 cm in length in the case of the segments 127, 146 and somewhat shorter in the case of segments 32 and 160. The loop configurations of Figures 11 and 12 may be any desired length but typically are such that the loop approximates the size of the caterpillar design of Figures 3, 4 and 8.

Figure 10 illustrates an alternate infusion system to that of Figure 8, or the like, and includes an infusion port 192 above a catheter or sheath seal and lock (not shown) and the electrode conducting wires as at 192 and possibly a guidewire and/or control member 194 can be provided with passage through the system to the proximal controls.

This invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to
5 construct and use embodiments of the example as required. However, it is to be understood that the invention can be carried out by specifically different devices and that various modifications can be accomplished without departing from the scope of the invention itself.

CLAIMS

I claim:

1. A recording and ablation catheter system for creating linear lesions in the right atrial chamber of a heart comprising:
 - (a) a guide member for navigating the catheter in the vascular system of a patient;
 - (b) a flexible distal working catheter area associated with a main catheter or sheath, said working catheter area having spaced distal and proximal catheter riders having bores adapted to slidably thread relatively adjustable to each other over a wire member such that the working catheter area intermediate said distal and said proximal catheter riders is unattached and can be adjustably arcuately flexed according to the relative separation of said rider bores on said guidewire to assume a desired shape to address an inner surface of a chamber; and
 - (c) a plurality of serial electrodes carried by said working catheter.
2. The apparatus of claim 1 including means to adjust the electrodes of the adjustable working catheter area to assume a substantially linear contact pattern with respect to a contacted shaped chamber surface in a desired direction.
3. The apparatus of claim 1 wherein the sheath is rotatable with respect to the guide member.
4. The apparatus of claim 1 wherein the adjustable working catheter can access the right atrial chamber from either the inferior vena cava or the superior vena cava.
5. The apparatus of claim 1 further comprising stop means for limiting travel of the distal end of the working catheter.
6. A recording and ablation catheter system for a vascular cardiac catheter creating linear lesions to produce segmentation in the right atrial chamber comprising:

-15-

- (a) a vascular navigating guidewire designed to protrude from the distal end of a main catheter or sheath;
- 5 (b) a flexible distal working catheter section having a proximal and a distal end and adapted to be deployed from a main elongated catheter or sheath having a lumen capable of containing said working catheter section and a plurality of spaced separately connected serial electrodes on said
- 10 working catheter section;
- (c) wherein the distal end of said working catheter section is capable of assuming an arcuate shape of controllable curvature capable of contacting an internal surface of a cardiac chamber and
- 15 assuming a posture enabling production of substantially linear ablation lesions along a chamber surface using a plurality of spaced electrodes.

7. The apparatus of claim 6 wherein the distal end

20 of the working catheter section is further slidably attached to the guidewire and wherein travel limiting means is provided to limit the distal travel of the distal end of the working catheter section so that further relative distal axial displacement of the more proximal portion of

25 the distal working catheter section produces an arcuate protrusion thereof.

8. The apparatus of claim 7 wherein the distal working catheter section forms a predetermined central loop shape upon deployment.

30 9. The apparatus of claim 8 wherein the loop is selected from right and left handed.

10. The apparatus of claim 6 wherein the distal working catheter is adapted to be deployed by being advanced through an opening in the distal portion of the

35 sheath.

11. The apparatus of claim 8 wherein the size of the loop is adjustable.

12. The apparatus of claim 6 wherein the electrodes are arranged in spaced pairs wherein the intra-pair spacing is less than the inter-pair spacing.

13. A method of mapping and ablating surface tissue in the right atrial cardiac chamber comprising the steps of:

- 10 (a) navigating a main catheter or sheath carrying a deployable flexible distal catheter section through the vascular system of a patient of interest;
- (b) causing the distal end of the catheter to enter the right atrial chamber optionally through the superior vena cava or the inferior vena cava;
- 15 (c) wherein:
 - 20 (1) the flexible distal working catheter section has a proximal and a distal end and adapted to be deployed from the main elongated catheter or sheath, the main catheter or sheath having a lumen capable of containing said working catheter section and a plurality of spaced serial electrodes on said working catheter section,
 - 25 (2) wherein the distal end of said working catheter section has an arcuate shape of controllable curvature capable of contacting an internal surface of a cardiac chamber and assuming a posture enabling production of substantially linear ablation lesions along a chamber surface;
- 30 (d) causing the distal area of the working catheter section to assume a controlled curvature contact with a desired inner atrial surface such that a relatively linear ablation lesion can be formed by energizing a plurality of said spaced serial electrodes;
- 35 (e) ablating tissue to form linear lesions where indicated; and

-17-

(f) reversing steps (b) and (a).

14. The method of claim 15 further comprising the
step of using the distal working catheter to map electrical
activity prior to ablation to determine precise ablation
5 location.

1/3

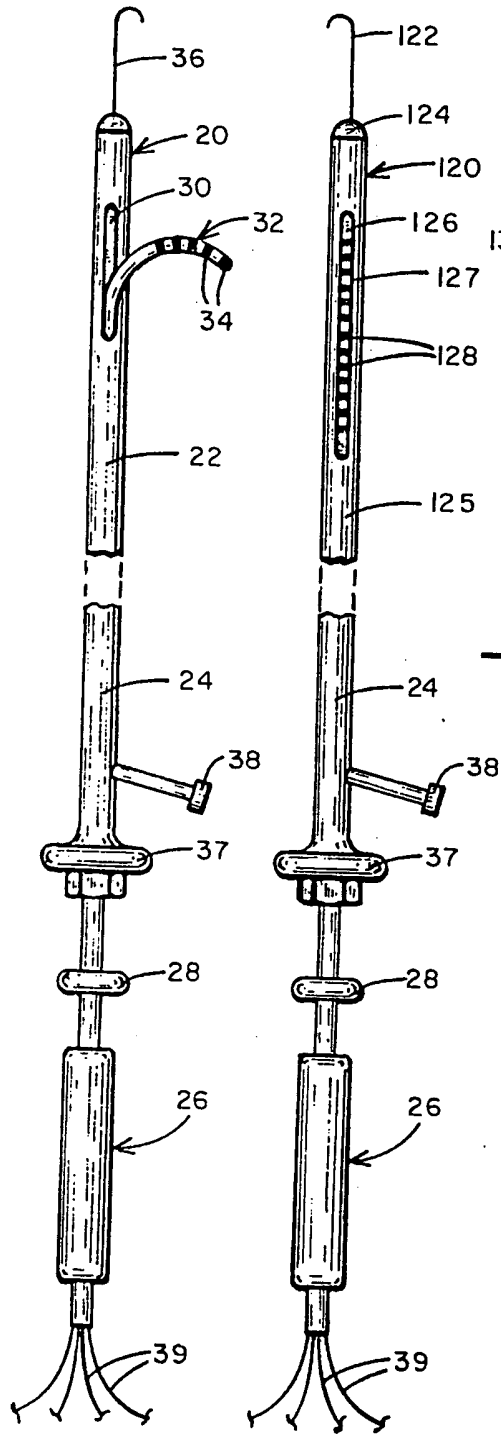


Fig. 1 Fig. 2

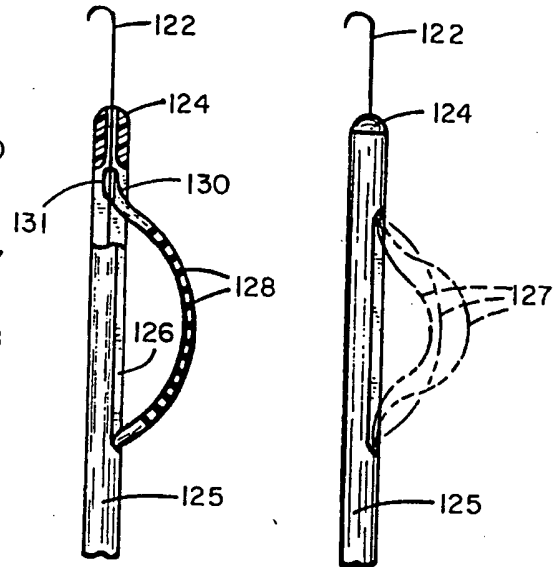


Fig. 3 Fig. 4

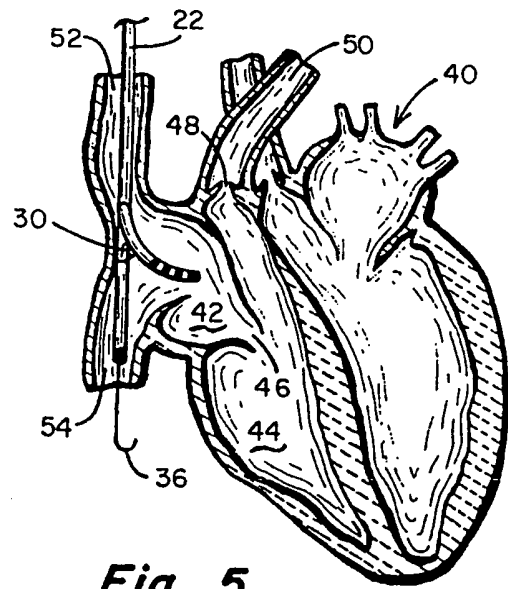


Fig. 5

2/3

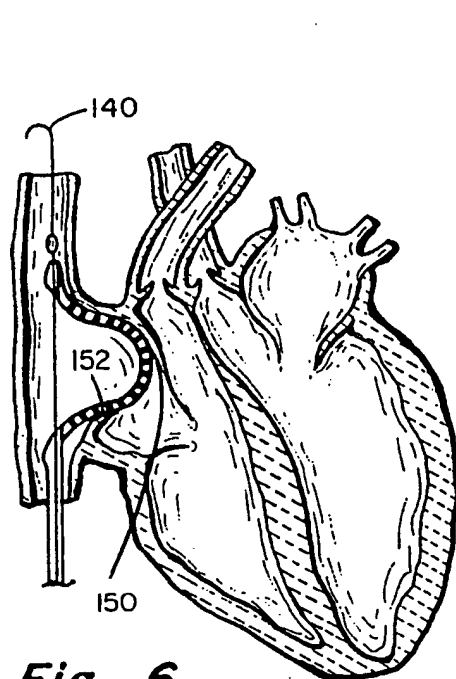


Fig. 6

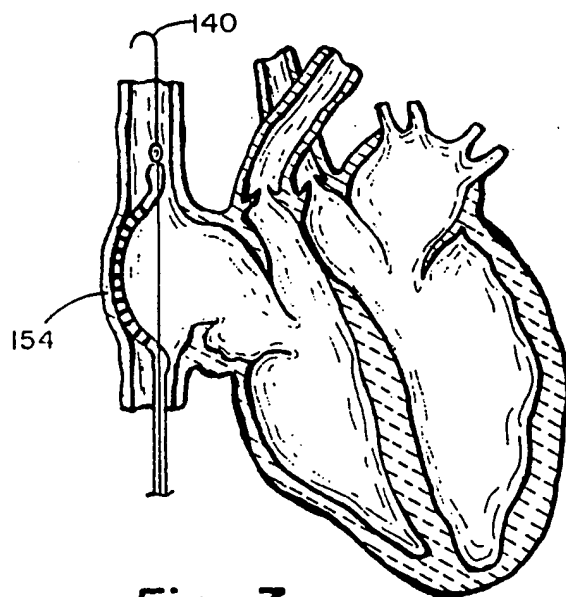


Fig. 7

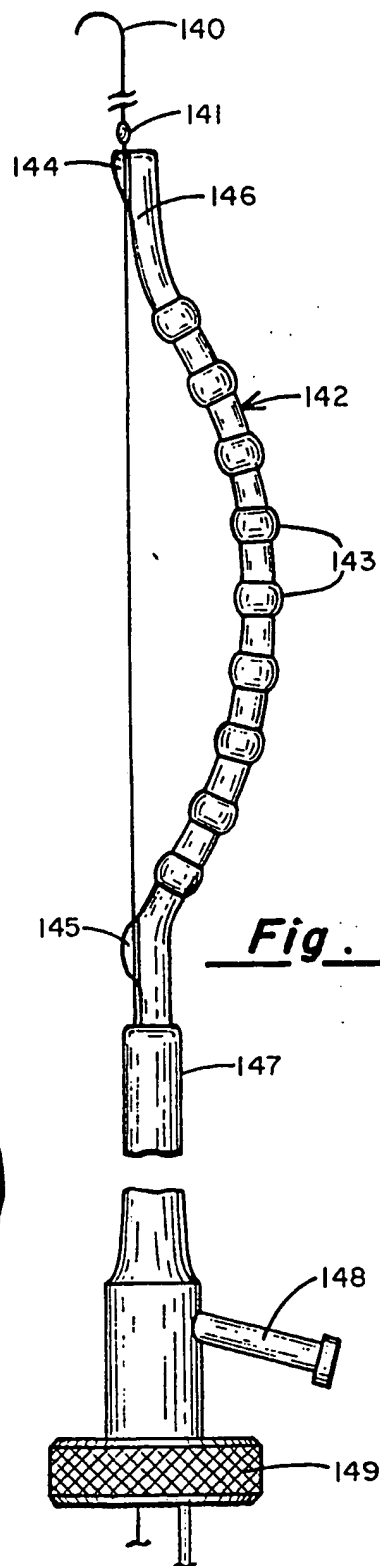


Fig. 8

3/3

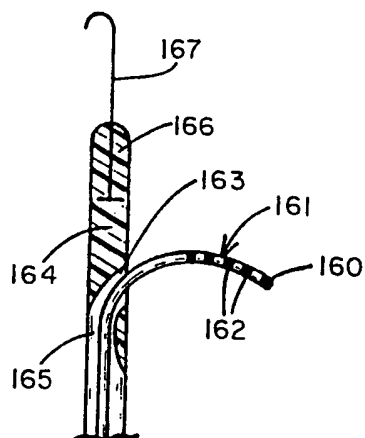


Fig. 9

Fig. 10

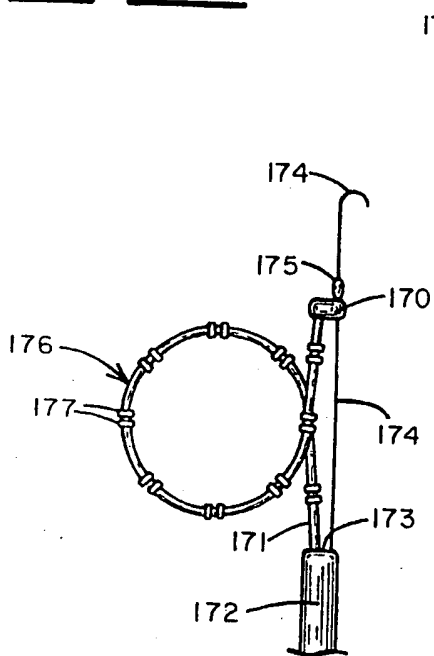
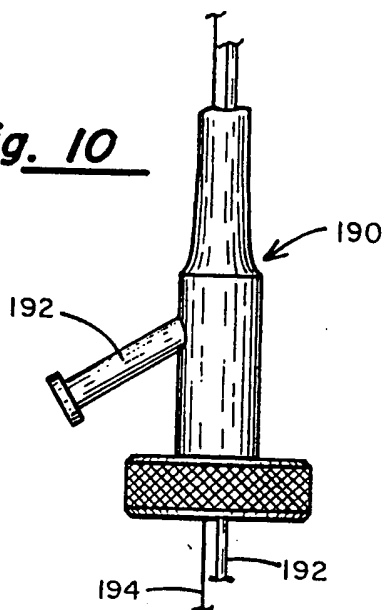


Fig. 11

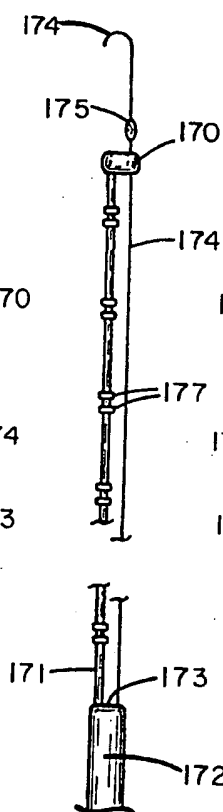


Fig. 13

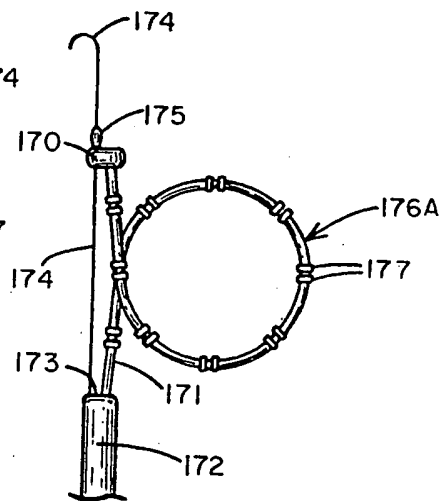


Fig. 12

INTERNATIONAL SEARCH REPORT

Inte. l. application No.
PCT/US94/13932

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/04

US CL :128/642

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/642; 607/122,125,126,98,99

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US,A, 4,699,147(CHILSON ET AL) 13 OCTOBER 1987, see entire document	6-11 ----- 12-14
Y	US,A, 5,228,442(IMRAN) 20 JULY 1993, see entire document	12-14
A	US,A, 4,660,571(HESS ET AL) 28 APRIL 1987, see entire document	1-14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G*	document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

23 JANUARY 1995

Date of mailing of the international search report

31 MAR 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

BRIAN CASLER

Telephone No. (703) 308-0858

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :

A61B 5/04

A1

(11) International Publication Number:

WO 95/15115

(43) International Publication Date:

8 June 1995 (08.06.95)

(21) International Application Number: PCT/US94/13932

(22) International Filing Date: 1 December 1994 (01.12.94)

(30) Priority Data:

08/161,920

3 December 1993 (03.12.93)

US

(71)(72) Applicant and Inventor: AVITALL, Boaz [US/US]; 4868
North Ardmore Avenue, Milwaukee, WI 53217 (US).(74) Agent: MERSEREAU, C., G.; Haugen and Nikolai, P.A., 820
International Centre, 900 Second Avenue South, Minneapolis,
MN 55402 (US).(81) Designated States: AU, CA, JP, European patent (AT, BE,
CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT,
SE).

Published

*With international search report.**With amended claims and statement.*

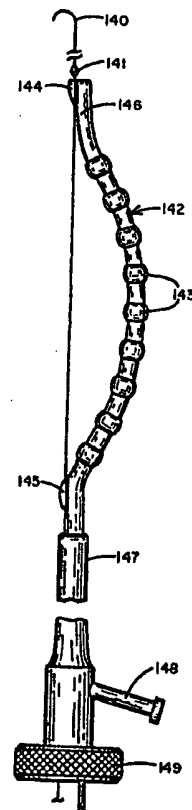
Date of publication of the amended claims and statement:

29 June 1995 (29.06.95)

(54) Title: ATRIAL MAPPING AND ABLATION CATHETER SYSTEM

(57) Abstract

A recording and ablation catheter system for creating linear lesions in the right atrial chamber of a heart is disclosed which includes an array of readily controlled electrodes (143) arcuate distal working catheter shapes that are easily deployed to contact the inner wall surface of the recording and mapping of impulses and thereafter facilitates sustained contact so that linear lesions can be produced from an array of mapping and ablation electrode devices (143) serially spaced along the working catheter shape.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TC	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

AMENDED CLAIMS

[received by the International Bureau on 31 May 1995 (31.05.95);
original claims 1-14 replaced by amended claims 1-20 (5 pages)]

1. A recording and ablation catheter system for
creating linear lesions in a heart chamber comprising:
 - 5 (a) an hollow vascular catheter or sheath;
 - (b) a guide member for aiding the navigation of said
catheter or sheath in the vascular system of a
patient;
 - 10 (c) a guide-mounted flexible inner catheter carried
by and deployable from a lumen of said vascular
catheter or sheath, said inner catheter having a
working catheter section having spaced distal and
proximal catheter riders having bores adapted to
15 slidably thread over said guide member and being
relatively adjustable to each other such that the
working catheter section intermediate said distal
and said proximal catheter riders is unattached
and can be adjustably arcuately flexed according
to the relative separation of said rider bores on
20 said guide member to assume a desired shape to
address an inner surface of a chamber; and
 - (d) a plurality of serial electrodes carried by said
working catheter section.
2. The apparatus of claim 1 including means to
25 adjust the electrodes of the adjustable working catheter
section to assume a substantially linear contact pattern
with respect to a contacted shaped chamber surface in a
desired direction.
3. The apparatus of claim 1 wherein said working
30 catheter section is rotatable with respect to the guide
member.
4. The apparatus of claim 1 further comprising stop
means for limiting travel of the distal end of the working
catheter.
- 35 5. The apparatus of claim 4 wherein the adjustable
working catheter section is of a length and said stop means
located such that it can readily access a desired surface

of the right atrial chamber from either the inferior vena cava or the superior vena cava.

6. The apparatus of claim 1 wherein said electrodes are separately connected thereby energizable in any combination.

7. The apparatus of claim 1 wherein the length of said working catheter section is from about 5 cm to about 15 cm.

8. The apparatus of claim 1 wherein said electrodes are about 4 mm in length.

9. The apparatus of claim 8 wherein the inter-electrode distance is about 4 mm.

10. A recording and ablation catheter system for a vascular cardiac catheter for creating linear lesions to produce segmentation in a heart chamber comprising:

- (a) an hollow elongated vascular catheter or sheath having a lumen for containing an inner catheter;
- (b) a vascular navigating guide member disposed to protrude from a distal end of said catheter or sheath;
- (c) a single member flexible inner catheter having a distal working catheter section having a proximal and a distal end and adapted to be deployed from said elongated catheter or sheath, wherein the distal portion of said working catheter section further comprises a guide member port that is further slidably attached over the guide member and further comprising travel limiting means for limiting travel of the distal end of the working catheter section along the guide member so that further relative distal axial displacement of a more proximal portion of the distal working catheter section produces an arcuate protrusion thereof; and
- (d) a plurality of spaced separately connected serially situated electrodes on said single member working catheter section.

11. The apparatus of claim 10 wherein the distal working catheter section forms a predetermined central loop shape upon deployment.

12. The apparatus of claim 11 wherein said loop shape is one selected from the group consisting of right and left handed loops.

13. The apparatus of claim 11 further comprising means to adjust the diameter of said loop.

14. The apparatus of claim 10 wherein said catheter or sheath further comprises a distal opening and wherein said distal working catheter section is adapted to be deployed by being advanced through said distal opening in said catheter or sheath.

15. The apparatus of claim 14 wherein the distal working catheter section forms a predetermined central loop shape upon deployment.

16. The apparatus of claim 14 wherein said loop shape is one selected from the group consisting of right and left handed loops.

17. The apparatus of claim 14 further comprising means to adjust the diameter of said loop.

18. The apparatus of claim 10 wherein the electrodes are arranged in spaced pairs having an intra-pair spacing and an inter-pair spacing and wherein said intra-pair spacing is less than said inter-pair spacing.

19. A recording and ablation catheter system for a vascular cardiac catheter for creating linear lesions to produce segmentation in a heart chamber comprising:

(a) an hollow elongated vascular catheter or sheath having a lumen for containing an inner catheter;

(b) a vascular navigating guidewire disposed to protrude from a distal end of said catheter or sheath;

(c) an inner catheter comprising a single member flexible distal working catheter section having a proximal and a distal end and adapted to be deployed from said elongated catheter or sheath

in a heart chamber, said distal working catheter section being contained at the proximal end and having a free, unattached distal end and a plurality of spaced separately connected serially situated electrodes on said single member working catheter section; and

- (d) wherein the distal end of said single member flexible distal working catheter section is of a predetermined generally arcuate shape assumed upon deployment.

20. A method of mapping and ablating surface tissue in the right atrial cardiac chamber comprising the steps of:

- (a) navigating a main catheter or sheath carrying a deployable flexible distal working catheter section through the vascular system of a patient of interest;
- (b) causing the distal end of the catheter to enter the right atrial chamber optionally through a vessel selected from the group consisting of the superior vena cava and the inferior vena cava;
- (c) wherein said main catheter or sheath comprises:
- (1) a vascular navigating guidewire disposed to protrude from a distal end of said main catheter or sheath;
 - (2) a single member flexible working catheter section having a proximal and a distal end and adapted to be deployed from said main catheter or sheath via a lumen therein for containing said working catheter section and a plurality of spaced separately connected serially situated electrodes on said single member working catheter section;
 - (3) means for causing said working catheter section to assume an arcuate shape of controlled curvature for contacting an internal surface of said chamber and

assuming an adjustable posture enabling positioning for the production of substantially linear ablation lesions along a predetermined line of the chamber surface using said plurality of spaced electrodes.

5

(d) causing the distal area of the working catheter section to assume a controlled curvature in contact with a desired inner atrial surface such that a relatively linear ablation lesion can be formed by energizing a plurality of said spaced serial electrodes;

10

(e) adjusting and positioning said single member working catheter section to ablate desired areas of said inner atrial surface;

15

(f) ablating tissue to form linear lesions where indicated; and

(g) reversing steps (b) and (a).

STATEMENT UNDER ARTICLE 19

The new replacement pages contain a new slate of claims, claims 1-20, which are believed to define the invention in clearer and more concise terms; and, in this regard, applicant believes the present claims also clearly distinguish over USA, 4,699,147 (Chilson et al) cited as category "X" against claims 6-11 and category "Y" against claims 12-14, together with USA, 5,228,442 (Imran), combined as category "Y" against claims 12-14.

The applied references, Chilson et al '147 and Imran '442, clearly describe and disclose cardiac catheter devices of a type employing radially diverging multiple-member or multiple-element deployable electrode-carrying systems designed to be deployed so as to expand radially within the chamber pushing outward against the walls of the chamber thereby assuming a random position. However, once expanded within the designated heart chamber, these devices circumferentially contact areas of the inner surface substantially at random depending on the position of the device when expanded and cannot thereafter be repositioned without great difficulty. This means that large surface areas of the interior of a chamber between positioned strands are not accessible for either mapping or ablation without collapsing and attempting to reposition the system which may not be successful. It should be kept in mind that the heart is continually beating during these procedures and the selected chamber expanding and contracting continually during placement and expansion of the devices. Time is of the essence in accomplishing the desired procedure.

The adjustable arcuate shape of the single member electroded device of the applicant's invention is far easier to manipulate as it does not assume a posture based on the circumferential expansion of multiple radially diverse strands as does Chilson et al '147, for example. The single member may be rotated about the central guide and repositioned or positionally adjusted with a great deal less difficulty. Neither reference alone or in combination produces this phenomenon.

The invention enables and facilitates the accurate mapping and production of linear lesions as desired to segment the electrical conductivity of aspects of the heart muscle more accurately. Thus, it is believed that the present system in its several forms clearly involves an inventive step with respect to devices previously known.

THIS PAGE BLANK #JSPZL

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)